

**SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY
AND WINTEC PHARMACEUTICAL, INC.**

Wintec Pharmaceutical, Inc. ("Licensee") and the State Board of Pharmacy ("Board") enter into this settlement agreement for the purpose of resolving the question of whether Licensee's license as a drug distributor will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo,¹ the parties hereto waive the right to a hearing by the Administrative Hearing commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Licensee acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence on mitigation of discipline; and the right to request the recovery of attorney's fees incurred in defending this action against its license. Being aware of these rights provided to Licensee by operation of law, Licensee knowingly and

¹ All statutory references are to the 2000 Revised Statutes of Missouri, as amended, unless other wise stated.

voluntarily waives each and every one of these rights and freely enters into this settlement agreement and agrees to abide by the terms of this document, as they pertain to it.

Licensee acknowledges that it has received a copy of the investigation report and other documents relied upon by the Board in determining there was cause for discipline, along with citations to law and/or regulations the Board believes were violated. For purpose of settlement only, Licensee stipulates that the factual allegations contained in this settlement agreement are true and stipulates with the Board that Licensee's drug distributor license, license number 900078, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

Joint Stipulation of Facts

1. The Board is an agency of the State of Missouri created pursuant to Section 338.140, RSMo, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.
2. Licensee has a drug distributor license, license number 900078. The Licensee's Missouri license is current and active, and was so at all times relevant herein.
3. L. Wayne Winchester is the president, owner, and manger-in-charge of Wintec.
4. Wintec is registered with the Federal Drug Administration ("FDA"), registration No. 1938138.
5. The FDA initiated an inspection at Wintec sometime between August 28, 2007 and September 11, 2007.

6. Violations were documented by the FDA in their FDA-483 forms.
7. Winchester acknowledged to the FDA his understanding of the violations, and promised to correct them.
8. He was informed of his obligation to comply with the laws and regulations administered by the FDA.
9. On or about October 22, 2007, the Board opened an investigation into the drug distributor activities at Wintec.
10. On or about January 7, 2008, the Board interviewed Winchester at Wintec to address the observations the FDA found.
11. The Board found drugs were not being stored under appropriate conditions of temperature, which affects the drug's identity, strength, quality, and purity.
12. Between October 10, 2006 and March 15, 2007, documented temperatures for the warehouse were consistently below 68 degrees Fahrenheit.
13. Drugs were stored at documented temperatures above 77 degrees Fahrenheit for 20 days in August 2007.
14. Following the FDA inspection of August 29, 2007 to September 11, 2007, drugs continued to be stored at documented temperatures below 68 degrees Fahrenheit in September 2007 and October 2007.
15. The thermometers at Wintec have never been calibrated, and there were no written procedures for their calibration.
16. There was no humidity recording equipment at Wintec, and there was no documentation to show that humidity has ever been recorded.

17. There was inadequate lighting for all areas of Wintec.
18. Wintec was cluttered with open boxes and miscellaneous items on the floor, preventing unhindered access to all areas where drugs were stored.
19. Licensee had no alarm system or any other adequate security policies or procedures written or unwritten to detect after hours access.
20. There were no written policies and procedures for any aspect of the company's operations.
21. There was no documentation to show that pest control treatments have been completed and maintained in the warehouse.
22. Licensee has a relationship of professional trust and/or confidence with its customers and the public at large.

Joint Conclusions of Law

1. Title 20 CSR 2220-5030(3), provides in part:

(B) The temperature of the facility where drugs are stored must be maintained within temperature requirements as provided for by the manufacturer or the latest edition of the *United States Pharmacopeia* (USP). Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, logs, or all of these, shall be utilized to document proper storage of prescription drugs[.]
2. Title 20 CSR 2220-5.030(1), provides in part:

(1) Drug distributors must maintain standards of practice that will ensure that only drugs of appropriate quality will be distributed to practitioners for further compounding and dispensing to the public. These standards shall be subject to periodic reviews through the board's inspection process.
3. Title 20 CSR 2220-5.030(3), provides in part:

(C) Appropriate housekeeping, sanitation, lighting, ventilation

and humidity of all areas where drugs are stored must be maintained.

10. Procedures must be in place to prevent, control and alleviate infestation by insects, rodents, birds or vermin of any kind.

...

13. All facilities shall be equipped with an alarm system to detect entry after hours.

4. Title 20 CSR 2220-5.030(3)(M), provides in part:

(M) Wholesale drug and pharmacy distributors shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories[.]

5. Section 196.015, RSMo, states in pertinent part:

The following acts and the causing thereof within the state of Missouri are hereby prohibited:

(1) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;

6. Section 196.095 states in part:

A drug or device shall be deemed to be adulterer:

(2) If it has been produced, prepared, packed, or held under insantitray conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health[.]

7. By not storing the drugs under appropriate conditions of temperature and proper calibration, Wintec violated title 20 CSR 2220-5.030(3)(B) and 196.015, RSMo.

8. By not having humidity recording equipment, inadequate lighting, and clutter and miscellaneous items on the floor at Wintec, there was a violation of 20 CSR 2220-5.030(3)(C).

9. By not having an alarm system at Wintec, Wintec violated title 20 CSR 2220-5.030(3)(C)(13).

10. By not having documentation to show that pest control treatments have been completed and maintained at Wintec, Wintec violated title 20 CSR 2220-5.030(3)(C)(10).

11. By not having written policies and procedures for any of the aspects of Wintec's operations, Wintec violated title 20 CSR 2220-5.030(3)(M).

12. Wintec violated title 20 CSR 2220-5.030(1), in that Wintec did not maintain standards of practice that will ensure that only drugs of appropriate quality will be distributed to practitioners for further compounding and dispensing to the public.

13. Section 338.055, RSMo, states in pertinent part:

2. The board may cause a complaint to be filed with the Administrative Hearing Commission as provided by Chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his certificate or registration or authority, permit or license for any one or any combination of the following causes:

* * *

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

* * *

(6) Violation of, or assisting or enabling any person to violate, any provisions of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

(13) Violation of any professional trust or confidence;

* * *

14. Cause exists to discipline Wintec's drug distributor license pursuant to sections 338.055.2(5), (6), (13) and (15), RSMo.

Jointly Agreed Disciplinary Order

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of § 621.045.3, RSMo.

1. Licensee's license as a drug distributor, License No. 900078, is hereby **VOLUNTARILY SURRENDERED**, ALL INDICIA OF LICENSURE SHALL BE SURRENDERED on October 31, 2009, the effective date of this Settlement Agreement.

2. Licensee shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

3. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, and 610, RSMo.

4. Wintec shall return all indicia of licensure; i.e, the original wall-hanging certificate, the computer-generated 5" x 7" license, and the wallet card, to the Board office on or before October 31, 2009. Wintec shall not engage in any activity or conduct in the State of Missouri for which a license to operate a drug distributor is required after the effective date of this agreement. Wintec shall not be open for business after the effective date of the voluntary surrender to conduct business for which a drug distributor license is required. Wintec MAY remain open for business to conduct any business that does not include the distribution of drugs for which a license is required, or the physical presence of individuals within the licensed drug distribution area of the facility.

5. This Settlement Agreement does not bind the Board or restrict the remedies available to it concerning any future violations by Wintec of Chapter 338, Sections 338.010 to 338.198, RSMo, as amended, or the regulations promulgated thereunder, or of the terms and conditions of this Settlement Agreement.

6. This Settlement Agreement does not bind the Board or restrict the remedies available to it concerning facts or conduct not specifically mentioned in this Settlement Agreement that are not now known to the Board or may be discovered.

7. Each party agrees to pay all their own fees and expenses incurred as a result of this case, its litigation, and/or its settlement.

8. The terms of this settlement agreement are contractual, legally enforceable, and binding, not merely recital. Except as otherwise contained herein, neither this settlement agreement nor any of its provisions may be changed, waived, discharged, or terminated,

except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.


9. Licensee hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former Board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. Section 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this settlement agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this settlement agreement in that it survives in perpetuity even in the event that any court of law deems this settlement agreement or any portion thereof void or unenforceable.

10. The Board releases and forever discharges Wintec, its parents, subsidiaries and affiliates, and their directors, officers, shareholders, agents and employees, of and from any and all liability, claims, actions, causes of actions, fees, costs and expenses, or proceedings of any kind or nature, that are based on the facts of this agreement and any other facts that are currently known by the Board, whether arising in tort, contract laws, equity, or whether based upon a violation of any statute, law, regulation or ordinance, whether state, local, federal or administrative, including but not limited to §§ 196.015, 196.095, 338.055, RSMo., and Chapter 338, and/or 20 CSR 2220-5.030, which arise out of or relate any way to Wintec's drug distributor activities in the State of Missouri.


11. Licensee understands that it may, either at the time the settlement agreement is signed by all parties, or within fifteen (15) days thereafter, submit the agreement to the Administrative Hearing Commission for determination that the facts agreed to by the parties constitute grounds for disciplining Licensee's drug distributor license. If Licensee desires the Administrative hearing Commission to review this agreement, Licensee may submit its request to: Administrative Hearing Commission, Truman State Office Building, Room 640, 301 W. High Street, P.O. Box 1557, Jefferson City, Missouri 65102.

12. If Licensee requests review, this settlement agreement shall become effective on the date the Administrative Hearing Commission issues its order finding that the settlement agreement sets forth cause for disciplining Licensee's license. If Licensee does not request review by the Administrative Hearing Commission, the settlement agreement goes in to effect fifteen (15) days after the document is signed by the Executive Director of the Board.

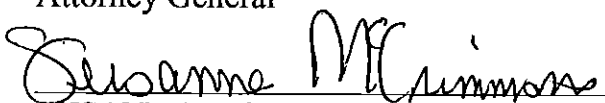
LICENSEE

By: 
Wintec Pharmaceutical, Inc.
L. Wayne Winchester
President
Date 8/10/09

STATE BOARD OF PHARMACY


Kimberly Grinston
Executive Director
State Board of Pharmacy
Date 9/28/09

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**ATTORNEYS FOR THE MISSOURI
STATE BOARD OF PHARMACY**